

VA HUMAN STUDIES
APPROVAL REQUIREMENTS

Deadlines: The Human Studies Subcommittee of the Research & Development Committee meets on the 4th Tuesday of every month. The deadline for submission for that meeting is the 2nd Friday of every month.

Principal Investigator: _____

Title of Project: _____

PI Check	Document	Research Check
	Protocol (if available, as submitted to IRB)	
	Investigator's Brochure (if applicable, as submitted to IRB)	
	BRAAN protocol (old RPN)	
	HIPAA authorization form and/or waiver	
	IRB Approval letter	
	Approved IRB VA Form 10-1086 consent form	
	VA contact and VA phone number on consent form	
	Research Methods Form, Pharmacy (if applicable)	
	Attestation Form, procedures & devices (If applicable)	
	Pharmacy sign-off on Methods Accountability Form (if applicable)	
	VA Pharmacy use initiation fee letter (if applicable)	
	Clinical Trials Data Sheet	
	Outpatient Clinic Profile	
	Investigational Drug Information Record VA Form 10-9012 (if applicable)	
	Clinical Research Projects Form	
	Biohazard Safety Form (if applicable)	
	CITI, GCP, and VA HIPAA training completed by all key research personnel (annually)	
	If investigator is physician, is credentialed at the VA Medical Center.	
	Research staff have WOC appointment to the VA if not an employee	